REMARKS

This Amendment is responsive to the Office Action dated March 3, 2004. In this Amendment, Applicants have amended claims 1, 2, 8, 14, 16, 17, 26, 31, 32, 34, and 42, canceled claims 3, 19, 27, and 43, and added new claims 59-64. Claims 1, 2, 4-18, 20-26, 28-42, and 44-64 are now pending.

Information Disclosure Statement

As a preliminary matter, Applicant directs the Examiner's attention to Applicant's submission of an Information Disclosure Statement on April 30, 2004, and request that the Examiner consider the references cited in the Information Disclosure Statement. Also, with this Amendment, Applicants submit a copy of a PCT Written Opinion recently received in the counterpart PCT application for the Examiner's consideration.

Allowable Subject Matter

In the Office Action, the Examiner allowed claims 36-41 and 49-58. The Examiner also indicated that claims 34 and 35 would be allowable if rewritten to overcome the rejections under 35 U.S.C. 112, second paragraph, and to include all of the limitations of the base claim and any intervening claims. Finally, the Examiner indicated that claims 4, 6, 8, 12, 13, 15-20, 28, 30-33 and 43-48 are objected to as being dependent on a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. In this response, claims 8 and 31 have been rewritten in independent form to include the limitations of claims 1 and 26, respectively. Accordingly, claims 8 and 31 should now be allowable.

Claim Objection Under 37 C.F.R. § 1.75(b)

Claims 5 and 29 are objected to under 37 C.F.R. § 1.75(b), as the Examiner perceived that the claims do not "differ substantially" from previously recited claims 3 and 27, respectively. Applicants respectfully traverse this objection. To expedite prosecution, however, Applicants have canceled claims 3 and 27. Accordingly, this objection should now be moot. Therefore, Applicants request a withdrawal of the objection.

Claim Rejection Under 35 U.S.C. § 112

In the Office Action, the Examiner rejected claims 34 and 35 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have amended claim 34 for purposes of clarification. Applicants submit that claim 34, as amended, particularly points out and distinctly claims the subject matter, as required by 35 U.S.C. § 112, second paragraph. Claim 35 is dependent on claim 34, and similarly satisfies the requirements of 35 U.S.C. § 112, second paragraph.

Claim Rejections Under 35 U.S.C. § 102

In order to support an anticipation rejection under 35 U.S.C. § 102(e), it is well established that a prior art reference must disclose each and every element of a claim. This well known rule of law is commonly referred to as the "all-elements rule."[1] If a prior art reference fails to disclose any element of a claim, then rejection under 35 U.S.C. § 102(e) is improper. [2]

Fernandez, Lee, and Muraca fail to disclose all limitations set forth in claims 1-3, 5, 7, 9-11, 14, 21-27, 29, and 42, particularly to the extent those claims have been amended. For at least these reasons, Fernandez, Lee and Muraca fail to establish a prima facie case of anticipation of Applicant's claims 1-3, 5, 7, 9-11, 14, 21-27, 29, and 42 under 35 U.S.C. § 102(e).

Claims 1-3, 5, 7, 9-11

In the Office Action, the Examiner rejected claims 1-3, 5, 7, and 9-11 under 35 U.S.C. § 102(e) as being anticipated by Fernandez et al. (US 2001/0022615). Applicants respectfully traverse the rejection, to the extent it may be considered applicable to the amended claims. Fernandez fails to disclose all of features required by the claimed invention, as set forth in 35

[1] *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (CAFC 1986) ("it is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention").
[2] *Id. See also Lewmar Marine, Inc. v. Barient, Inc.* 827 F.2d 744, 3 USPQ2d 1766 (CAFC 1987); *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (CAFC 1990); *C.R. Bard, Inc. v. MP Systems, Inc.*, 157 F.3d 1340, 48 USPQ2d 1225 (CAFC 1998); *Oney v. Ratliff*, 182 F.3d 893, 51 USPQ2d 1697 (CAFC 1999); *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 57 USPQ2d 1057 (CAFC 2000).

U.S.C. § 102(e), and provides no teaching that would have suggested the desirability of modification to include such features.

For example, Fernandez fails to teach or suggest a system for communicating medical information, comprising a medical device installed with a version of software and a software agent communicatively coupled to the medical device for interacting with the medical device, wherein the software agent interacts with the medical device irrespective of correspondence to the version of software installed on the medical device, as required by Applicants' claim 1, as amended. Moreover, Fernandez fails to suggest incorporation of a software agent that accesses a directory in the medical device to invoke one or more objects having well-known names in the directory and thereby access information in the medical device. Therefore, Fernandez fails to establish a prima facie case of anticipation with respect to claim 1 and claims 2, 3, 5, 7, and 9-11 that depend from claim 1.

In regard to claim 1, the Examiner characterized Fernandez as describing a system for communicating between a medical device having input sensors 44 and a software agent in software 66 residing in processor/controller 6, as shown in FIGS. 2 and 3 of Fernandez. However, Fernandez does not teach or suggest a software agent interacting with a medical device irrespective of correspondence to the version of software installed on the medical device, as recited by Applicants' claim 1. In fact, Fernandez states "controller user may provide input to specify or request current or future monitoring or surveillance of one or more certain location or object. In this manner, software 66 is configured or updated." Fernandez, pg. 4, para. [0037], emphasis added.

From the above passage, it is clear that communication in the Fernandez system requires configuration and updating of software 66, and does not support interaction irrespective of correspondence to the version of installed software. Hence, Fernandez does not describe interaction between a software agent and a medical device regardless of correspondence between versions of software, but instead teaches altering a software agent to conform to the version of software installed on the medical device. Therefore, Fernandez is directly at odds with the requirements of Applicants' claim 1.

In addition to the deficiencies discussed above, Fernandez makes no mention of the use of a software agent that accesses a directory in the medical device to invoke one or more objects

having well-known names in the directory and thereby access information in the medical device, as set forth in amended claim 1. Applicants' disclosure describes software which includes a device interface to expose medical information such that the medical information can be accessed by any generation of the software agent. As set forth in Applicants' disclosure, for example, a "way to achieve this is to provide a number of objects having well-known names (or predefined names) whereby any software agent may use the well-known name of an object to execute the object to retrieve medical information, write medical information, or both." Page 3, para. [0030]. One of ordinary skill in the art would have had no appreciation of such a feature without access to Applicants' own disclosure. In view of this additional shortcoming, Fernandez would not support a prima facie case of anticipation with respect to claim 1.

In summary, Fernandez does not disclose or suggest all of the features of Applicants' claim 1. Therefore, Applicants respectfully request withdrawal of the rejection. Claims 2-3, 5, 7, and 9-11 depend from independent claim 1. For at least the reasons discussed above with respect to claim 1, dependent claims 2-3, 5, 7, and 9-11 are also in condition for allowance.

Claims 14, 21-27, 29

In the Office Action, the Examiner rejected claims 14, 21-27, and 29 under 35 U.S.C. § 102(e) as being anticipated by Lee (US 6,442,432). Applicant respectfully traverses this rejection. Lee fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(e), and provides no teaching that would have suggested the desirability of modification to include such features.

For example, Lee fails to teach or suggest a system for communicating medical information comprising a therapeutic device installed with a version of software, a software agent to present a user interface to communicate with the therapeutic device, and an interface for communicatively coupling the therapeutic device to the software agent irrespective of correspondence to the version of software of the therapeutic device, wherein the software agent accesses a directory in the medical device to invoke one or more objects having well-known names and thereby access data in the medical device, and the interface has a therapeutic portion that exposes data from the therapeutic device and a software agent portion that obtains the data

so that the user interface is invoked upon receiving the data, as recited by Applicants' independent claim 14, as amended.

Furthermore, contrary to independent claim 26, as amended, Lee fails to teach or suggest a system for remotely communicating with a medical device, comprising a defibrillator for storing data and being installed with a version of software, and a personal digital assistant being operative to communicate with the defibrillator to access the data irrespective of correspondence to the software version of the defibrillator, wherein the software agent accesses a directory in the medical device to invoke one or more objects having well-known names in the directory and thereby access the data in the medical device.

In regard to claim 14, the Examiner stated that Lee describes a system (FIG. 1 of Lee) for connecting implantable medical devices to remotely located monitoring/control devices comprising features of a therapeutic device (IMD) 112, an "interface medical unit" 116, and a "device agent software module." However, Lee does not teach the interface communicatively coupling the therapeutic device to the software agent irrespective of correspondence to the version of software of the therapeutic device, as recited by Applicants' claim 14. Lee states "a device agent software module may be selected from remote expert server 136 to interface with a particular type or model of IMD 112...an initial IMD 112 identification stage precedes the selection of device agent module." Lee, Col. 16, ll. 63-Col. 17, ll. 4, emphasis added. Furthermore, Lee states "the interface medical device is preconfigured to work only with the specific device(s) implanted in an individual host patient." Lee, Col. 17, ll. 6-8, emphasis added.

Clearly, Lee does not discuss interaction between the software agent and the therapeutic device irrespective of correspondence to the version of software. Rather, Lee appears to represent the antithesis of the claimed invention. In particular, according to Lee, software versions must be synchronized for proper communication. Moreover, Lee makes no mention of a software agent that accesses a directory in the medical device to invoke one or more objects having well-known names and thereby accesses data in the medical device, as set forth in amended claim 14. In view of these differences, Lee fails to establish a prima facie case of anticipation with respect to claim 14. For at least the reasons described above, dependent claims 21-25 are also in condition for allowance.

In regard to claim 26, the Examiner asserted that Applicants' claim reads on the scenario where IMD 112 may be an implantable defibrillator in communication with personal digital assistant (PDA) 138, as shown in FIG. 1 of Lee. As discussed above, however, Lee does not teach or suggest a personal digital assistant being operative to communicate with the defibrillator to access the data irrespective of correspondence to the software version of the defibrillator, as recited by Applicants' claim 26. On the contrary, Lee describes a software agent, such as within a PDA, that is selected to communicate with a particular type or model of IMD. In Lee, it appears that a different software agent or version is required to communicate with a different type or model of IMD. Lee does not teach or suggest each and every feature of Applicants' claim 26. For at least these reasons, clam 26 is in condition for allowance. In addition, claims 27 and 29 depend from independent claim 26, and are also in condition for allowance.

Claim 42

In the Office Action, the Examiner rejected claim 42 under 35 U.S.C. § 102(e) as being anticipated by Muraca (US 2002/0055917). Applicant respectfully traverses the rejection, to the extent it may be considered applicable to claim 42, as amended. Muraca fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(e), and provides no teaching that would have suggested the desirability of modification to include such features.

For example, Muraca fails to teach or suggest a terminal comprising a data storage device for storing a set of presentation tools, a user interface invokable by a presentation tool, and an interface for importing data stored in the medical device and for allowing the user interface to configure the medical device irrespective of the version of software of the medical device, wherein the interface exposes a directory of objects on the medical device so that each object can be accessed, each object referencing data relating to the medical device, and wherein the data to configure the medical device is structured in a language that contains the data and that describes the data through textual tags, as recited by Applicants' claim 42, as amended.

In support of the rejection, the Examiner stated that Muraca describes a method and apparatus using a master control file for easing computer software interoperability in medical devices. The Examiner further stated that the computer terminal 242 (FIG. 8 of Muraca) includes a Master Control File 216, which enables the terminal/computer to interface with various

disparate software operating systems. However, Muraca does not describe an interface for importing data stored in the medical device and for allowing the user interface to configure the medical device, as recited by Applicants' claim 42.

In contrast, Muraca merely describes a method for communicating between computer terminals with disparate software operating systems, but does not describe a user interface capable of configuring a medical device. For example, Muraca states "[t]he radiologist system receives cases from the sonographer, views active cases, requests more scans (attach audio or text note), initiates audio calls (audio portion of video conferencing), initiates video calls (video conference audio and video), releases a patient, and views history." Muraca, para. [0383]. As can be seen from the previous statement, Muraca requires a computer terminal operator to perform the requested functions of the medical device.

Moreover, Muraca provides no teaching that would have suggested an interface that exposes a directory of objects on a medical device so that each object can be accessed, each object referencing data relating to the medical device, wherein the data to configure the medical device is structured in a language that contains the data and that describes the data through textual tags, as further set forth in amended claim 42.

Muraca fails to teach or suggest each and every feature of Applicants' claim 42. Therefore, claim 42 is in condition for allowance. Applicants request withdrawal of the rejection.

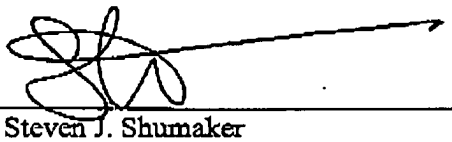
New Claims

In this Amendment, Applicants have added new claims 59-64. Claims 59-61 are dependent on claim 1. Claim 62 is a new independent claim. Claims 63 and 64 are dependent on new claim 62.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: 5-28-04

By: 

SHUMAKER & SIEFFERT, P.A.
8425 Seasons Parkway, Suite 105
St. Paul, Minnesota 55125
Telephone: 651.735.1100
Facsimile: 651.735.1102

Name: Steven J. Shumaker
Reg. No.: 36,275

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

SHUMAKER, Steven J.
SHUMAKER & SIEFFERT, P.A.
8425 Seasons Parkway
Suite 105
St. Paul, MN 55125
ETATS-UNIS D'AMERIQUE

PCT

WRITTEN OPINION
(PCT Rule 66)

D: 5-28-04

Date of mailing *(day/month/year)*	28.04.2004
Applicant's or agent's file reference: 1023-185WO01	**REPLY DUE** **within 1 month(s)** from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2002/035166	01.11.2002	10.12.2001

International Patent Classification (IPC) or both national classification and IPC
G06F19/00, G06F19/00

Applicant
MEDTRONIC PHYSIO-CONTROL MANUFACTURING CORP.

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☒	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☐	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 10.04.2004

Name and mailing address of the international preliminary examining authority:
European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d

Authorized Officer
Sisk, A

Formalities officer (incl. extension of time limits)
Schall, H

WRITTEN OPINION International application No. PCT/US2002/035166

I. Basis of the opinion

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed")*:

Description, Pages

1-13 as originally filed

Claims, Numbers

1-58 as originally filed

Drawings, Sheets

1-9 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   ☐ the language of publication of the international application (under Rule 48.3(b)).
   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.
   ☐ filed together with the international application in computer readable form.
   ☐ furnished subsequently to this Authority in written form.
   ☐ furnished subsequently to this Authority in computer readable form.
   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:
   ☐ the claims, Nos.:
   ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 1-58

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 1-58 are so unclear that no meaningful opinion could be formed *(specify)*:

   see separate sheet

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the Standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

Re Item I
Basis of the report

The basis of this opinion is the application as originally filed.

Re Item III
Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

a. Although claims 1, 14, 26, 36, 42, 49, 54 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection.

Hence, claims 1, 14, 26, 36, 42, 49, 54 do not meet the requirements of Article 6 PCT and therefore no opinion will be established with regard to novelty, inventive step and industrial applicability.

b. Furthermore, the following clarity objections are raised.

c. Claims 1, 26, 42 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claims attempt to define the subject-matter in terms of the result to be achieved, "irrespective of the version of software installed", which merely amounts to a statement of the underlying problem. The technical features necessary for achieving this result should be added.

d. The following terms are vague and unclear and leave the reader in doubt as to the meaning of the technical features to which they refer, thereby rendering the definition of the subject-matter of said independent claims unclear (Article 6 PCT).
(i) In claim 1, the term "software agent".
(ii) In claim 1, the term "communicatively coupled".
(ii) In claim 14, the term "to present a user interface to communicate".

(iii) In claim 14, the term "an interface".
(iv) In claim 14, the term "a therapeutic portion that exposes data from the therapeutic device".
(v) In claim 36, the term "a common interface".
(vi) In claim 42, the term "an interface for importing data".

e. However, to assist the applicant in filing a new set of claims and also with a view to the requirements of Article 33(1)-(5)PCT, an assessment of prior art has been made:

f. The following documents have been cited in the international search report
D1: US-A-5 800 473
D2: WO 98 24212 A
D3: WO 01 45793 A

g. According to the description and in so far as it can be understood, it appears that the present application is directed to a system for transferring data to and from a medical device and configuring said device, whereby the medical device publishes or exposes its functionality, such that the configuring or data receiving program can invoke the functionality of the medical device.

h. Two alternate ways of exposing the functionality of the medical device are disclosed in the application, the provision of an application programming interface (API) which may be used to control the medical device, or the publishing of the name/names of medical device objects/functionality so that this functionality can be invoked.

i. Document D1, which is provisionally considered to be the closest prior art, discloses a system for transferring data to and from a medical device and configuring said medical device. The medical device maintains a list of software objects which encapsulate the functionality it provides (see Figure 1 and Col 2, lines 19-28). An external device such as a programmer accesses this list of objects to establish the capabilities of the device and invokes the functionality of the device by means of these objects (see claim 6). Therefore D1 discloses both of the suggested implementations of the system of the present application, the publication of a name through which an object can be invoked and the publication of a programming interface for an object (see col 5, lines 15 to 45). Thus D1 discloses features equal or equivalent to the system of the present application.

j. Furthermore, for the sake of completion, document D2 discloses a communications protocol used by a medical device by means of which the capabilities of the device can be established, data can be transferred and the device can be configured. All devices provide a simple interface of 4 commands, ENQ, ID, DATA and TEST (page 18, line 2 to page 19, line 10) therefore the system of D2 exposes these basic operations as a programming interface.

k. Document D3 discloses a communication system between a medical device and a computer whereby devices publish their services using JINI and Java RMI (see page 8, lines 3 to 11 and page 18, lines 9 to 23).

The use of distributed object methodologies such as JINI, RMI, CORBA, COM, and DCOM for the purpose of enabling distributed software objects to work together is well known and the principles of these methodologies, such as exposing an objects functionality by means of a programming interface and publishing the names of available objects in Naming Services, are also well known.

l. If amendments are filed, the applicant should comply with the requirements of Rule 66.8 PCT and indicate the basis of the amendments in the documents of the application as originally filed (Article 43(2)(b) PCT) otherwise these amendments may not be taken into consideration for the establishment of the international preliminary examination report.

The attention of the applicant is drawn to the fact that if the application contains an unnecessary plurality of independent claims, no examination of any of the claims will be carried out.

m. In order to facilitate the examination of the conformity of the amended application with the requirements of Article 34(2)(b) PCT, the applicant is requested to clearly identify the amendments carried out, no matter whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based (see also Rule 66.8(a) PCT).

n. Independent claims should be in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (D1) being placed in the preamble (Rule 6.3(b)(i)

PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

If, however, the applicant is of the opinion that the two-part form would be inappropriate, then reasons therefor should be provided in the letter of reply. In addition, the applicant should ensure that it is clear from the description which features of the subject-matter are already known in combination from the prior art (see the PCT Guidelines, III-2.3a).